



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/595,977

06/14/2007

Mark Ashby

1001.2219102

1136

28075 7590 08/16/2010
CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

MASHACK, MARK F

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

08/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,977	Applicant(s) ASHBY ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27,29-33,40-49,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,27,40-49,61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 6/15/2010. Claims 1, 27, 29-33, 40-49, and 61-62 are pending. Claims 29-33 have been withdrawn.

Response to Arguments

1. Applicant's arguments filed 6/15/2010 have been fully considered but they are not persuasive. Applicant argues that **Nash** does not disclose of a release member being capable of "positioning and releasing the flexible plug intravascularly". Examiner disagrees. The release member as discussed below positions the plug intravascularly and releases it from the sheath. Applicant argues that the combination of **Nash** and **Hannam** is improper because **Nash** teaches of an anchor that is "sufficiently rigid" such that "it is resistant to deformation". Examiner disagrees. That property is shared by the anchor of **Hannam** since he teaches of the anchor being "sufficiently rigid such that... it is resistant to deformation to preclude it from bending and passing back through the puncture or incision" (Column 7, Lines 30-34). Applicant argues "spacer 78 does not appear to couple the two elements". Examiner disagrees. The term "couple" is a very broad term and element 78 extends between the two elements.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 3773

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 43-45** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims appear to combine embodiments that were not originally intended to be combined.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1, 27, 40-46, 61-62** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al. ("Nash" US 5,700,277)** in view of **Hannam et al. ("Hannam" US 5,649,959)**.

Regarding Claim 1, Nash discloses an apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner pressure is greater than the outer lumen pressure, the apparatus comprising:

a flexible plug (element **32** excluding element **52**) having a center, top surface, and a bottom surface;

a release mechanism **30, 36** including a hemostatic material (Column 2, Lines 1-4) having a bottom surface attached to the top surface near the center of the flexible plug (Fig 3), and a resilient extension member **36**, the resilient extension member has a transverse aperture **62** therein and a suture **34** passing through the aperture to secure the suture to the resilient extension member, the release mechanism positioning and releasing the flexible plug intravascularly at the blood vessel puncture site;

the suture can be considered “not directly attached to the flexible plug” since the plug can be considered element **32** excluding the portion **52** that engages the suture since the ends and bottom of the element **32** anchor the apparatus to the subject (Fig 9) while portion **52** engages the suture (Fig 19).

Nash discloses all of the claimed limitations except for the plug being sized to circumferentially cover the blood vessel puncture site and being sufficiently flexible to conform to and seal the blood vessel puncture site. However, **Hannam** teaches of a similar apparatus comprising a plug with those properties (Column 7, Lines 34-46). It would have been obvious to modify the anchor with these properties in order to prevent injury to the vessel and prevent the release of the hemostatic vessel into the vessel.

Regarding Claim 27, the outer periphery of the hemostatic material can be considered a biocompatible “dissolvable capsule”.

Regarding Claim 40, **Nash** discloses an apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner pressure is greater than the outer lumen pressure, the apparatus comprising:

a flexible plug **32** having a center, top surface, and a bottom surface;

a hemostatic material to seal the blood vessel puncture site (Column 2, Lines 1-4); and

a connector (elements **36**, or **78**) disposed between the disk and the hemostatic body, the connector positioned within a wall of the blood vessel puncture site (Fig 6, 9).

Nash discloses all of the claimed limitations except for the plug being sized to circumferentially cover the blood vessel puncture site and being sufficiently flexible to conform to and seal the blood vessel puncture site. However, **Hannam** teaches of a similar apparatus comprising a plug with those properties (Column 7, Lines 34-46). It would have been obvious to modify the anchor with these properties in order to prevent injury to the vessel and prevent the release of the hemostatic vessel into the vessel.

Regarding Claim 41, the connector (**36**, **78**) has a smaller diameter than the flexible disk diameter and the hemostatic body diameter (Fig 9). **Regarding Claim 42-44**, the apparatus further comprises a release mechanism comprising a resilient extension member **36** having an aperture at the top **62** a suture **34** which is secured to

the hemostatic body **30** with knot **58**. An adhesive is an obvious variant of a knot. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element for another to yield predictable results. If that is not convincing, it was well known in the art at the time of the invention to reinforce a knot with an adhesive. **Regarding Claim 45**, the apparatus further comprising a suture **34** looped through the aperture. **Regarding Claim 61**, the bottom of the hemostatic material is removably attached to the top surface of the flexible plug (Fig 3). **Regarding 62**, the suture is secured to the resilient extension member by tying one end of the suture **58a** to itself after passing through the aperture.

7. **Claims 46-49** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash** in view of **Hannam** as applied to claim 1 above, and further in view of **Kensey et al.** ("**Kensey**" US 5,441,517).

Nash in view of **Hannam** disclose all of the claimed limitations except for the resilient extension member being made of hemostatic material and being encapsulated. However, **Kensey** teaches of thea similar resilient extension member **40** comprising a hemostatic agent (Column 13, Lines 43-49, and Column 9, Lines 25-33). The outer periphery of the resilient extension member is considered a "dissolvable capsule" and the center would comprise a hemostatic material.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773